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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KUBELIK, ANNE R	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/646,532	ROBERT ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *4-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election with traverse of Group I (claims 1-3 and 16) in the response filed 29 September 2003 is acknowledged.

The traversal is on the ground(s) that there does not appear to be any homology between the sequence of Sullivan et al and the claimed subject matter. This is not found persuasive because the sequence of Sullivan et al comprises a modification or fragment of SEQ ID NOs:1, 2 or 3.

The traversal is on the ground(s) that the inventive concept is not ADPG transporters per se, but the structural feature represented by the amino acid sequences of claim 1. This is not found persuasive because all ADPG transporters would comprise a modification or fragment of SEQ ID NOs:1, 2 or 3.

Claims 4-15 are withdrawn from consideration as being drawn to a non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

2. Claims 1-3 and 16 are objected to because of the following informalities:

In claim 1, line 3, and claim 16, line 2, -consisting-- should be inserted after "group".

In claims 2-3, line 1, a comma should be inserted before "wherein".

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-3 and 16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to an ADP-glucose transporter protein, which is a product of nature.

Claims 1-3 and 16, as written, do not sufficiently distinguish over proteins as they exist in nature because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). It is suggested that the claims be modified to refer to the hand of the inventor, *e.g.* by replacing "A" in claims 1 and 16 with --An purified-- as taught by page 12 of specification. See MPEP 2105.

5. Claims 1-3 and 16 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are drawn to a ADP-glucose transporter protein comprising a modification or fragment of any of SEQ ID NOs:1-3.

While the specification suggests transforming a plant with a nucleic acid encoding the protein to alter starch production and starch quality in the plant (pg 4, paragraph 2, to pg 6. paragraph 1), these methods require the nucleic acid encoding the protein, not the isolated protein itself.

The specification provides no specific asserted for the isolated protein, and there is no well established utility for the protein. ADP-glucose transporter protein transports ADP-glucose

across cell membranes (see, for example, Shannon et al, 1998, Plant Physiol. 117:1235-1252, abstract), but does not enzymatically convert ADP-Glucose to another compound. It is apparent that extensive further research, not considered to be routine experimentation, would be required before one skilled in the art would know how to use the claimed invention. It has been established in the courts that a utility that requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use is not a substantial utility:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point-where specific benefit exists in currently available form, there is insufficient justification for permitting an application to engross what may prove to be a broad field (*Brenner v. Manson,* 383 U.S. 519 (1966)).

Accordingly, the claimed invention lacks a "real-world" use.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-3 and 16 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8. Claims 1-3 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to ADP-glucose transporter proteins comprising a modification or fragment of any of SEQ ID NOs:1-3, wherein the ADP-glucose transporter proteins are from any source.

The instant specification, however, only provides guidance for isolation of an ADP-glucose transporter from wheat amyloplasts and its reconstitution in liposomes (example 1).

The instant specification fails to provide guidance for the sequence of ADP-glucose transporter proteins comprising a modification or fragment of any of SEQ ID NOs:1-3, wherein the ADP-glucose transporter proteins are from any source.

The instant specification fails to provide guidance for which amino acids of the wheat ADP-glucose transporter can be altered and to which other amino acids, and which amino acids must not be changed, to maintain ADP-glucose transporter activity of the protein. The specification also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional enzyme.

Making "conservative" substitutions (*e.g.*, substituting one polar amino acid for another, or one acidic one for another) does not produce predictable results. Lazar et al (1988, Mol. Cell. Biol. 8:1247-1252) showed that the "conservative" substitution of glutamic acid for aspartic acid at position 47 reduced biological function of transforming growth factor alpha while "nonconservative" substitutions with alanine or asparagine had no effect (abstract). Similarly, Hill et al (1998, Biochem. Biophys. Res. Comm. 244:573-577) teach that when three histidines that are maintained in ADP-glucose pyrophosphorylase across several species are substituted with the "nonconservative" amino acid glutamine, there is little effect on enzyme activity, while the substitution of one of those histidines with the "conservative" amino acid arginine drastically

reduced enzyme activity (see Table 1). All these mutated proteins, however, would have at least 95% identity to the original protein. The nucleic acids encoding all these mutated proteins, however, would hybridize under high stringency to the nucleic acids encoding the original protein.

Given the claim breath, unpredictability in the art, undue experimentation, and lack of guidance in the specification as discussed above, the instant invention is not enabled.

9. Claims 1-3 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a multitude of ADP-glucose transporter proteins comprising a modification or fragment of any of SEQ ID NOs:1-3. The specification does not describe the entire protein sequence of any ADP-glucose transporter protein encompassed by the claims, and the structural features that distinguish all such proteins from other proteins are not provided.

Hence, Applicant has not, in fact, described ADP-glucose transporter proteins comprising a modification or fragment of any of SEQ ID NOs:1-3, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

> A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials .... Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by it principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-3 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 1 is indefinite in its recitation of "modification". The extent to which the sequences are modified and the amino acids, inserted, deleted or substituted are unclear.

Claims 1 and 16 are indefinite in their recitation of the phrase starting with "comprising" in line 2. It is not clear what the phrase is intended to modify - activity? protein? By position in the claims, the phrase modifies "comprising".

Claim 16 is ungrammatical in its recitation of "said protein being obtainable".

Claim 16 is indefinite in its recitation of "according to the protocol of example 1". The claims should not refer to the specification, but should set forth the active, positive steps involved in the method/process.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Sullivan et al (1991, Plant Cell 3:1337-1348) taken with the evidence of Shannon et al (1998, Plant Physiol. 117:1235-1252).

Sullivan et al teach a protein from maize; this protein would comprise a modification or fragment of at least one of SEQ ID NOs:1-3 (Figure 5). Shannon et al teach that the protein is a ADP-Glucose transporter and has a molecular weight of about 38kD (pg 1249, right column to pg 1250, left column).

14. Claims 2 and 16 are free of the prior art, given the failure of the prior art to teach or suggest an ADP-Glucose transporter comprising one of SEQ ID NOs:1-3.

Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm. Sometime in January 2004, the examiner's phone number will change to 571-272-0801.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
December 18, 2003